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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,997	06/11/2004	Mark A. Johanson	22956-302 (MIT-169CON)	3996
21125 7590 08/11/2009 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER WOO, JULIAN W	
			ART UNIT 3773	PAPER NUMBER
			NOTIFICATION DATE 08/11/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/709,997	Applicant(s) JOHANSON ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-6 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable Simon (5,346,497) in view of Strukel et al. (5,725,495). Simon discloses the invention substantially as claimed. Simon discloses, at least in figures 1, 2, 4-9 and 13 and in col. 4, line 58 to col. 5, line 42; an apparatus including a sheath (3) including a distal end having a cutting edge (5), a tooth (12) extending towards the inner bore in a direction substantially orthogonal to the cutting edge, and markings on the outer surface (8) that may correspond to an amount of insertion into bone tissue. However, Simon does not disclose a tube with proximal and distal ends and at least one recess or aperture spaced apart from the distal end and extending at least part way from an inner surface of the tube to an outer surface of the tube or beginning a predetermined distance away

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from the distal end of the tube and running toward the proximal end of the tube.

However, Simon does disclose that a "remainder" of an "infusion/aspiration device" is applied within the lumen of the sheath. Strukel et al. teach, at least in figures 20A, 23A, 25A, 26A, and 27A and col. 6, lines 43-56 and col. 7, lines 13-32; an infusion/aspiration device, where the device includes a sheathed tube (16) with proximal and distal ends and a plurality of recesses or apertures (18) each extending from an inner surface of the tube to an outer surface of the tube and running towards the proximal end of the tube and beginning a predetermined distance away from the distal end of the tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Strukel et al., to modify the apparatus of Simon, so that it includes a tube as claimed. Such a tube would allow the efficient aspiration of cut tissue and/or irrigation fluid and even aid in the emulsifying of tissue in, for example, certain types of cataract surgery.

Simon also does not disclose that the tube has a mating element or handle at its proximal end and that the sheath includes a connector for removable engagement with the mating element. Strukel et al. further teach, at least in figures 28, 29, 51 and 52, that the tube (16) has a mating element (proximal shoulder-like portion of 16) or a handle removably engaged with a sheath (22 or 88), which includes a connector (proximal portion of 22 connected near a shoulder-like portion of 16 or area A of 88). It also would have been obvious to one having ordinary skill in the art at the time the invention was made, to modify the tube and sheath of Simon, so that they respectively have a mating element and connector as claimed. Such modifications would allow a

fluid-tight connection between the tube and sheath and prevent leakage of irrigation fluid from the apparatus and would provide a location for grasping and manipulation of the device.

Note: The introductory statement of intended use (“for harvesting plugs from bone tissue”) has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Simon or Simon in view of Strukel et al., which is capable of being used as claimed if one desires to do so. In other words, the recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simon (5,346,497) in view of Strukel et al. (5,725,495), and further in view of Torrie et al. (6,358,253). Simon in view of Strukel et al. discloses the invention substantially as claimed. Simon in view of Strukel et al. discloses an apparatus for harvesting tissue, but does not disclose an apparatus including a bone plug formed from articular cartilage and underlying bone tissue. Torrie et al. teach, at least in col. 7, line 39 to col. 8, line 21, an apparatus including a harvested bone plug (87) formed from articular cartilage (86) and underlying bone tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Torrie et al., to include a bone plug formed from articular cartilage and underlying bone tissue with the apparatus

of Simon in view of Strukel et al. Such a bone plug would allow the repair and replacement of bone that is covered with damaged cartilage.

Response to Amendment

4. Applicant's arguments with respect to claims 1-7 and 28 have been considered but are not persuasive. That is, the combination of Simon and Strukel indeed renders obvious claims 1-6 and 28. First, the Examiner agrees with the Applicant in that Simon discloses a device with a cutting element and/or irrigation fluid. The Examiner acknowledged as much in the rejection above. However, Simon does not disclose a tube having proximal and distal ends and at least one recess or aperture spaced apart from the distal end as claimed. In other words: Yes, Simon discloses a device with irrigation/aspiration, but Simon does not disclose the configuration of the device for irrigation/aspiration. Specifically in col. 5, lines 38-42, Simon states "And further means, also not shown and also contained in the remainder of the infusion/aspiration device, will be provided for aspirating, through the tube's [element 3] interior space 11 [characterized as a "lumen" by the Examiner in the rejection above], irrigating fluid and, e.g., pieces of the lens broken off by the device's cutting or abrading action during cataract surgery." Thus, the teachings of Strukel regarding a tube configuration (i.e., inter alia, at least one recess or aperture in the tube) and sheath were combined with Simon to cure the deficiencies of Simon. And one of ordinary skill in the art would combine the references, so that not only would a tube, as taught by Strukel, provide efficient irrigation/aspiration, it would also advantageously aid in the emulsification of tissue in cataract surgery. In short, the modification of Simon with the teachings of

Strukel indeed provides a beneficial result and an invention satisfactory for its intended purpose.

With respect to arguments regarding the teachings of Torrie: Torrie was only combined with Simon and Strukel for the specific teaching of the harvesting of bone tissue and cartilage, where Simon in view of Strukel discloses the harvesting of tissue from "various parts of the body." (Simon, col. 1, lines 12-20).

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773